Sub	ostitute for form 1449/PTO			Complete if Known		
				Application Number	10/551,643-Conf. #5446	
l IN	IFORMATION	1 DI	SCLOSURE	Filing Date	July 24, 2006	
l s	TATEMENT B	3Y /	APPLICANT	First Named Inventor	Giovanni Monteleone	
				Art Unit	1645	
	(Use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned	
Sheet	Sheet 1 of 3		Attorney Docket Number	GIU-001		

	U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
	A1*	US-5,654,004	08-05-1997	Okayama et al.					
	A2*	US-5,783,566	07-21-1998	Mislick					
	A3*	US-5,929,226	07-27-1999	Padmapriya et al.					
	A4*	US-6,096,722	08-01-2000	Bennett et al.					
	A5*	US-6,159,697	12-12-2000	Monia et al.					
	A6*	US-6,200,602	03-13-2001	Watts et al.					
	A7*	US-6,251,628	06-26-2001	Nakao et al.					
	A8*	US-6,455,689	09-24-2002	Schlingensiepen et al.					
	A9*	US-6,479,465	11-12-2002	Strober et al.					
	A10*	US-6,605,443	08-12-2003	Nakao et al.					
	A11*	US-6,794,367	09-21-2004	Tanida et al.					
	A12*	US-6,884,787	04-26-2005	Monia et al.					
	A13*	US-6,943,241	09-13-2005	Isogai et al.					
	A14*	US-20020177568	11-28-2002	Stinchcomb et al.					
	A15*	US-20050119203	06-02-2005	Steinbrecher et al.					
	A16*	US-20070042985	02-22-2007	Monteleone					

	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear					
	B1	WO-08/014400	01-31-2008	Genizon Biosciences Inc et al.						
	B2	WO-99/050296	10-07-1999	Eli Lilly and Company		1				

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. \(^1\) Applicant's unique citation designation number (optional). \(^2\) See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. \(^3\) Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \(^4\) For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \(^5\) Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \(^6\)

	NON PATENT LITERATURE DOCUMENTS							
Examiner Initials								
	C1	Agrawal, S., et al., "Antisense Therapeutics: Is it as Simple as Complementary Base Recognition?", Molecular Medicine Today, February 2000 (Vol. 6), pps. 72-81.						
	C2	Arsura, M., et al., "TGFβ1 Inhibits NF-κB/Rel Activity Inducing Apoptosis of B Cells: Transcriptional Activation of IκΒά, Immunity, Vol. 5, 31-40, July, 1996.						
	СЗ	Boirivant, M., et al., "Lamina Propria T Cells in Crohn's Disease and other Gastrointestinal Inflammation Show Defective CD2 Pathway-Induced Apoptosis," Gastroenterology, 1999: 116: 557-565.						
	C4 Boirivant, M., et al., "Oral Administration of Recombinant Cholera Toxin Subunit B Inhibits IL-							

Sub	ostitute for form 1449/PTO			Complete if Known		
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				Art Unit	1645	
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Sheet	Sheet 2 of 3		Attorney Docket Number	GIU-001		

	12-Mediated Murine Experimental (Trinitrobenzene Sulfonic Acid) Colitis," The Journal of Immunology, 2001.	
C5	Boirivant, M., et al., "Oxazolone Colitis: A Murine Model of T Helper Cell Type 2 Colitis Treatable with Antibodies to Interleukin 4," The Journal of Experimental Medicine, Vol. 188, No. 10, November 16, 1998, 1929-1939.	
C6	Christ, M., et al., "Immune Dysregularation in TGF-β1-Deficient Mice," The Journal of Immunology, 1994.	
C7	Fiocchi, C., "TGF-β/Smad Signaling Defects in Inflammatory Bowel Disease: Mechanisms and Possible Novel Therapies for Chronic Inflammation," The Journal of Clinical Investigation, Vol. 108, No. 4, August 2001.	
C8	Gorelik, L, et al., "Abrogation of TGFβ Signaling in T Cells Leads to Spontaneous T Cell Differentiation and Autoimmune Disease," Immunity, Vol. 12, 171-181, February, 2000.	
C9	Gorelik, L., et al., "Transforming Growth Factorβ in T-Cell Biology," Nature Reviews/Immunology, Vol. 2, January 2002.	
C10	Guerlavais, T., et al., "Use of Maldi-TOF Mass Spectrometry to Monitor Solid-Phase Synthesis of Oligonucleotides," Anal Bioanal Chem (2002) 374: 57-63.	
C11	Hahm, K. B., et al., "Loss of Transforming Growth Factor β Signalling in the Intestine Contributes to Tissue Injury in Inflammatory Bowel Disease," Gut 2001;49: 190-198.	
C12	Han, Seung H., et al., "Transforming Growth Factor-Beta 1 (TGF-β1) Promotes IL-2 mRNA Expression Through the Up-regulation of NF-κB, AP-1 and NF-AT in EL4 Cells," The Journal of Pharmacology and Experimental Therapeutics, Vol. 287, No. 3.	
C13	Hayashi, H., et al., "The MAD-related Protein Smad7 Associates with the TGF β Receptor and Functions as an Antagonist of TGF β Signaling," Cell, Vol. 89, 1165-1173, June 27, 1997.	
C14	Heldin, Carl Henrik, et al., "TGF-β Signalling from Cell Membrane to Nucleus Through SMAD Proteins," Nature, Vol. 390, 4 December 1997.	
C15	Lawrance, Ian Craig, et al., "Inflammation Location, But Not Type, Determines the Increase in TGF-β1 and IGF-1 Expression and Collagen Deposition in IBD Intestine," Inflammatory Bowel Diseases, Vol. 7, No. 1, February 2001.	
C16	Lawrance, Ian C., et al., "A Murine Model of Chronic Inflammation-Induced Intestinal Fibrosis Down-Regulated by Antisense NF-κΒ," Gastroenterology 2003:125:1750-1761.	
C17	Lesiak, Krystyna, et al., "2',5'Oligoadenylate: Antisense ChimerasSynthesis and Properties," Bioconjugate Chem. 1993, 4, 467-472.	
C18	Ludviksson, B.R., et al., "TGF-β Production Regulates the Development of the 2,4,6-Trinitrophenol-Conjugated Keyhold Limpet Hemocyanin-Induced Colonic Inflammation in IL-2-Deficient Mice," The Journal of Immunology, 1997.	
C19	Maggi, A., Biotecnologie Farmacolpgiche, 1998, Cap. 8: 125-131.	
C20	Maier, Martin A., et al., "Synthesis of Chimeric Oligonucleotides Containing Phosphodiester, Phosphorothioate, and Phosphoramidate Linkages," Organic Letters 2000, Vol. 2, No. 13, p. 1819-1822.	
C21	Monteleone, G., et al., "Blocking Smad7 Restores TGF-β1 Signaling in Chronic Inflammatory Bowel Disease," The Journal of Clinical Investigation, August 2001, vol. 108, No. 4, p. 601-609.	
C22	Neurath, M.F., et al., "Experimental Granulomatous Colitis in Mice is Abrogated by Induction of TGF-β-Medicated Oral Tolerance," J. Exp. Med., Vol. 183, June 1996, p. 2605-2616.	
C23	Neurath, M., et al., "TNBS-Colitis," Intern. Rev. Immunol., Vol. 19, p. 51-62.	
C24	Podolsky, D.K., "Inflammatory Bowel Disease," N. Engl. J. Med., Vol. 347, No. 6, August 8, 2002, p. 417-429.	
C25	Powrie, F., et al., "A Critical Role for Transforming Growth Factor-β but not Interleukin 4 in the	

Sub	ostitute for form 1449/PTO			Complete if Known		
				Application Number	10/551,643-Conf. #5446	
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Sheet	Sheet 3 of 3		Attorney Docket Number	GIU-001		

	Supression of T Helper Type 1-Mediated Colitis by CD45RBlow CD4+ T Cells," J. Exp. Med., Vol. 183, June 1996, p. 2669-2674.	
C26	Ragas, J.A., "A Comparative Study on Methods of Optimal Sample Preparation for the Analysis of Oligonucleotides by Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry," Analyst, 2000, 125, p. 575-581.	
C27	Read, S., et al., "Induction of Inflammatory Bowel Disease in Immunodeficient Mice by Depletion of Regulatory T Cells," Current Protocols in Immunology (1999) 15.13.1-15.13.10.	
C28	Sanborn, et al., "Biologic Therapy of Inflammatory Bowel Disease," Gastroenterology 2002:122:1592-1608.	
C29	Sanghvi, Y.S., et al., "Antisense Oligodeoxynucleotides: Synthesis, Biophysical and Biological Evaluation of Oligodeoxynucleotides Containing Modified Pyrimidines," Nucleic Acids Research, 1993, Vol. 21, No. 14, 3197-3203.	
C30	Seegers, D., et al., "Review Article: A Critical Approach to New Forms of Treatment of Crohn's Disease and Ulcerative Colitis," Aliment Pharmacol Ther 2002: 16(Suppl. 4): 53-58.	
C31	Shull, M.M., et al., "Targeted Disruption of the Mouse Transforming Growth Factor-β1 Gene Results in Multifocal Inflammatory Disease," Nature, Vol. 359, 22 October 1992, p. 693-698.	
C32	Wei, X, et al., "Synthesis and Characterization of Composite Nucleic Acids Containing 2',5'-Oligoriboadenylate Linked to Antisense DNA," Antisense & Nucleic Acid Drug Development 6:247-258 (1996).	
C33	Yang, X., "Targeted Disruption of SMAD3 Results in Impaired Mucosal Immunity and Diminished T Cell Responsiveness to TGF-β," The EMBO Journal, Vol. 18, No. 5, pp. 1280-1291, 1999.	

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Signature	Considered	

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